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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention

[60Day-12-0824]

Proposed Data Collections Submitted for  
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 and send comments to Kimberly S. Lane, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

### **Proposed Project**

BioSense 2.0 (OMB No.0920-0824, exp. 10/31/2012) - Revision - Office of Surveillance, Epidemiology, and Laboratory Services (OSELS), Public Health Surveillance and Informatics Program Office (PHSIPO) {Proposed} Centers for Disease Control and Prevention (CDC).

Background and Brief Description: The BioSense Program was created by congressional mandate as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and it was launched by the Centers for Disease Control and Prevention (CDC) in 2003. BioSense is a near real-time surveillance system that receives and processes electronic healthcare encounter data, including, chief complaints, final diagnosis codes, procedure codes, clinical laboratory, pharmacy prescription, and patient demographic data from participating public health jurisdictions' non-federal hospital emergency departments and inpatient facilities in addition to all United States Department of Defense (DoD) and Veterans Affairs (VA)

outpatient hospitals and clinics nationwide. The BioSense Program also receives pharmacy data from a private sector health information exchange firm and laboratory data from two national-level private sector clinical laboratories.

The BioSense Program is in the process of transitioning from the original BioSense application to the BioSense 2.0 application that has new governance, a new organizational structure, and a new process for data submission and management. The Association of State and Territorial Health Officials (ASTHO) has been funded through a cooperative agreement with CDC's Division of Notifiable Disease and Healthcare Information (DNDHI) within the Public Health Surveillance and Informatics Program Office (PHSIPO) of the Office of Surveillance, Epidemiology, and Laboratory Services (OSELs) to facilitate the governance of BioSense 2.0, and through a contract with a vendor, ASTHO will offer access and use of BioSense 2.0 on a voluntary basis to state, local, and territorial health jurisdictions.

Unlike the original BioSense application where participating organizations' data were processed and stored at CDC in the CDC owned and operated Information Technology Services Office's Mid-Tier Data Center on secure servers, all

data submitted by users in BioSense 2.0 will reside in a cloud-enabled, web-based platform that sits in the secure, private Government Cloud and is in compliance with the Federal Information Security Management Act. The platform will provide users with an exclusive secure space as well as tools for posting, receiving, controlling, analyzing, and sharing their public health surveillance information with other public health jurisdictions, CDC, or other public health partners. The public health jurisdiction will retain ownership of any data it contributes to its exclusive secure space within BioSense 2.0.

The BioSense 2.0 cloud also provides the CDC's BioSense Program its own exclusive secure space to receive, store, and analyze data. CDC has agreements with VA, DoD, two national-level private sector clinical laboratories, and a private sector health information exchange firm to provide healthcare encounter data to CDC's secure space for the purpose of national public health situation awareness and syndromic surveillance. These organizations automatically chose to share with CDC when they were recruited to submit data to the BioSense 2.0 cloud environment. Because they are not required to choose sharing permissions, collecting already existing healthcare encounter data submitted via electronic record transmission from them entails no burden hours.

In addition to providing a secure, exclusive space for use by CDC and secure, exclusive spaces for use by each participating state, local, and territorial public health jurisdiction, BioSense 2.0 provides a second secure space in the cloud for public health jurisdictions to share aggregate data with other participating jurisdictions and CDC. Whenever possible, the BioSense Program plans to share aggregate-level pharmacy and laboratory data with public health jurisdictions. To participate in the shared space, jurisdiction administrators must simply select from drop-down lists to choose their sharing permissions on the BioSense 2.0 application, and they will have the right at any time to revise the level of sharing permissions regarding the data in their secure space.

As part of access to the shared space, public health jurisdictions will be required to grant CDC access to, at minimum, aggregate level data (city, county, or state) from their jurisdiction that has been placed in the shared space. They must also agree that CDC may review data contributed to the shared space for public health practice and surveillance purposes.

In order to continue meeting the congressional mandate in the BioSense 2.0 application, the BioSense Program maintains 3

different types of information collection: (1) contact information (name, telephone number, email address, and street address) needed for recruitment of up to 20 participating public health jurisdictions to BioSense 2.0 per year; (2) one-time collection of information (name, email address, title, organizational affiliation, security questions, and password) to provide access to the BioSense 2.0 cloud and its tools for all appropriate users in participating jurisdictions and organizations, and (3) collection of already existing healthcare encounter data submitted to the cloud via electronic record transmission from participating public health jurisdictions' non-federal hospitals, VA, DoD, two national-level private sector clinical laboratories, and a private sector health information exchange firm. Though a large number of electronic records are transmitted from each entity each year, once the automated interfaces are set up for transmission (choosing sharing permissions), there is no human burden for record transmission.

This request is for a 3-year approval. There are no costs to survey respondents other than their time to participate.

## Estimates of Annualized Burden Hours

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
<b>Recruitment</b>				
State, Local, and Territorial Public Health Jurisdictions	20	1	1	20
Federal Government	2	1	1	2
Private Sector (national clinical laboratory corporations, and a private sector health information exchange company)	3	1	1	3
<b>Access to BioSense 2.0 Application</b>				
State, Local, and Territorial Public Health Jurisdictions	200	1	5/60	17
Federal Government	30	1	5/60	3
Private Sector	50	1	5/60	4
<b>Data Collection: Administrator Sharing Permissions</b>				
State, Local, and Territorial Public Health Jurisdictions	20	1	5/60	2
Federal Government	2	0	0	0
Private Sector (national clinical laboratory corporations, and a private sector health information exchange company)	3	0	0	0
<b>Total</b>				<b>51</b>

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